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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,869	07/02/2003	Melvyn Smith	23660/2	6642

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EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,869	SMITH, MELVYN	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 4-11, and 56, drawn to methods for the detection of an Epstein Barr Virus (EBV) nucleic acid in a sample using a probe that binds to SEQ ID NO: 1 or its complement, classified in class 435, subclass 6.

II. Claims 2, 3, and 12-19, drawn to methods for the detection of EBV nucleic acids in a sample comprising a step of PCR amplification using a primer pair and detection of the nucleic acid using a probe for SEQ ID NO: 1 or its complement, classified in class 435, subclass 91.2.

III. Claims 19-27, 34-35, 49-51, 54, 55, and 57-59, drawn to oligonucleotides binding to SEQ ID NO: 1 or its complement, classified in class 536, subclass 24.3.

IV. Claims 28-33, and 61, drawn to a primer pair for the amplification of a region of SEQ ID NO: 1 or its complement, classified in class 536, subclass 24.33.

V. Claim 52, drawn to methods for the quantification of EBV viral load in a sample comprising the use of a probe to SEQ ID NO: 1 to determine the amount of an EBV nucleic acid in a test sample and a control sample, classified in class 435, subclass 6.

VI. Claim 53, drawn to methods to monitor the efficacy of a drug for alleviating EBV infection comprising using a probe to SEQ ID NO: 1 or its complement to determine the amount of an EBV nucleic acid in a sample from a first patient

sample and from a second sample from a patent after commencement of therapy, classified in class 435, subclass 6.

VII. Claim 46, drawn to methods for making compositions for the detection of EBV nucleic acids comprising a probe, classified in class 536, subclass 24.32.

VIII. Claim 47, drawn to methods for making compositions for the detection of EBV nucleic acids comprising a forward primer for the sequence of SEQ ID NO: 1, classified in class 536, subclass 24.33.

IX. Claim 48, drawn to methods for making compositions for the detection of EBV nucleic acids comprising a primer pair, classified in class 536, subclass 24.33.

X. Claim 60, drawn to methods for making compositions for the detection of EBV nucleic acids comprising a reverse primer for the sequence of SEQ ID NO: 1, classified in class 536, subclass 24.33.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of each of Groups II, V, and VI are related as combination and subcombination with the inventions of Group I. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combinations as claimed do not require the particulars of the subcombination as claimed because they may rely on the additional method steps for patentability. The subcombination has separate utility in methods for the detection of viral nucleic acids.

3. The inventions of Groups I, II, and V-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions each relate to methods that perform a different function, and comprise different modes of operation. The methods are therefore distinct.

4. The inventions of Groups III and IV are either unrelated or related as combination and subcombination. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Certain of the inventions of these Groups are unrelated. These inventions are disclosed as useful to perform different functions. Further, in view of the use of oligonucleotides with different sequences, the inventions also have different modes of operation. Certain inventions in Group III are related as subcombination and combination with the inventions of Group IV. The combination may rely on the combination of any primer pair for patentability. The subcombinations each have separate utility as probes for the sequence of SEQ ID NO: 1.

5. The inventions of Groups III and IV and of Groups I, II, and V-X are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the different products may be used in any of the claimed inventions. The products are therefore distinct from each of the processes.

Species Election

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

If Applicant elects one of Groups I, II, V, VI, and VII above, Applicant is additionally required to elect one of the following species of EBV probes:

(a) the probe comprising SEQ ID NO: 2, or

(b) the probe comprising SEQ ID NO: 3.

If Applicant elects one of Groups II, IV, or IX, Applicant is additionally required to elect one each of a forward primer from species (c) and (d), and a reverse primer from species (e) and (f).

Species (c) and (d) represent the elected invention wherein the forward primer comprises either (c) SEQ ID NO: 4, or

(d) SEQ ID NO: 5.

Species (e) and (f) represent the elected invention wherein the reverse primer comprises either (e) SEQ ID NO: 6, or

(f) SEQ ID NO: 7.

If Applicant elects Group III above, Applicant is additionally required to elect one of species (a)-(f) above.

If Applicant elects Group VIII above, Applicant is additionally required to elect one of species (c) or (d) above.

If Applicant elects Group X above, Applicant is additionally required to elect on of species (e) or (f) above.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 19, 28, 52, 53, 46-48, and 60 are generic to the species within the respective Group.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Priority

7. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United Kingdom on April 24, 2003. It is noted, however, that applicant has not filed a certified copy of the 0309311.9 application as required by 35 U.S.C. 119(b).

Conclusion

8. Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. It is here noted that some of the restrictions requirements made above fall within the scope of PTO Linking claim practice. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn. Claim 1 is considered a linking claim between Groups I and the other Groups comprising the use of the indicated probe.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

JAMES HOUSEL 7/26/04
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